11/10/00 16:39:49 Via Fax -> 541 857 8872 ~~John A. Walker~~ Page 001

Paul Schlemit 7158

FYI

This message is to update you on our discussions with FDA regarding Lotronex ® (alosetron hydrochloride). We have previously notified you of the Public Citizen's Petition to the FDA that Lotronex be withdrawn from the market. We will be meeting with the FDA on Monday November 13th to review the available data on the safety profile of Lotronex. The FDA is considering further restrictions for distribution of Lotronex. Since Public Citizen has asked for withdrawal of the product this might be one of the topics for Monday.

We have confidence in the efficacy and safety profile of Lotronex in the treatment of appropriate female patients with diarrhea-predominant IBS. We are committed to taking further steps to support patient and physician understanding of appropriate patient selection, important safety information, and proper management of patients on Lotronex.

I have provided an Internet site and mailing address if you would like to comment to the FDA.

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services, Room 1-23
12420 Parklawn Drive
Rockville, Maryland 20857
FAX 301-827-6870

Or you can e-mail the FDA at fdadockets@oc.fda.gov

NOTE: BECAUSE THIS IS THE GENERAL DOCKET ADDRESS, PHYSICIANS SHOULD REFER TO THE DOCKET NUMBER IN THEIR EMAIL. THE DOCKET NUMBER IS:
Docket No. 00P-1499/CP1

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RE

I have 4 patients c IBS with x 25 years. Those with diarrhea dominant IBS state "Alosetron is the only medicine that has ever helped me!" Please keep it available for them.

Paul Schlemit MD

00P-1499

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